

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: BERNER et al.

APPLICATION NO.: 10/769,574

FILED: JANUARY 29, 2004

FOR: **GASTRIC RETENTIVE ORAL DOSAGE FORM WITH
RESTRICTED DRUG RELEASE IN THE LOWER
GASTROINTESTINAL TRACT**

EXAMINER: HOLT, A.

ART UNIT: 1616

CONF. NO: 8962

DECLARATION OF JENNY LOUIE-HELM AND BRET BERNER**UNDER 37 C.F.R. § 1.132**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, Jenny Louie-Helm and Bret Berner, declare and affirm as follows:

1. We are co-inventors of the subject matter described and claimed in the above-identified application (herein "the instant application"). The instant application claims the benefit of an application filed October 25, 2001.
2. The claimed subject matter in the instant application relates to a method for delivering an active agent by orally administering to a patient in a fed mode dosage form comprised of a polymer matrix comprised of a hydrophilic polymer, wherein the dosage form swells upon imbibition of water to a size effective to promote gastric retention and maintains its size for an extended period of time before being diminished by erosion.
3. We are named co-authors of the June 2001 publication entitled PHARMACOKINETICS OF CIPROFLOXACIN GASTRIC RETENTIVE (GR™) TABLETS IN



HEALTHY VOLUNTEERS, published in the *Proceedings for Controlled Release Society* (herein "the Louie-Helm publication"). The Louie-Helm publication describes a dosage form containing ciprofloxacin that swells after oral administration to a size sufficient for gastric retention.

4. The subject matter described in the Louie-Helm publication was conceived or invented by us, Jenny Louie-Helm and Bret Berner.

We declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

06 MAR 09

Date

Jenny Louie-Helm

Jenny Louie-Helm

Date

Bret Berner

HEALTHY VOLUNTEERS, published in the *Proceedings for Controlled Release Society* (herein "the Louie-Helm publication"). The Louie-Helm publication describes a dosage form containing ciprofloxacin that swells after oral administration to a size sufficient for gastric retention.

4. The subject matter described in the Louie-Helm publication was conceived or invented by us, Jenny Louie-Helm and Bret Berner.

We declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Date

Jenny Louie-Helm

5/6/99
Date


Bret Berner